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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,597	10/11/2007	John E. Davies	1716-30/AMK	7537

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EXAMINER	
EPPS -SMITH, JANET L	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,597	DAVIES ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Smith	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-9 are pending for examination.

Claim Objections

2. Claim 8 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim 8 not been further treated on the merits.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

5. Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Baksh et al. (WO02/086104A1; ¶ numbers cited below are taken from the US patent application 20040137612).

Baksh et al. teach the following: "[0048] FIG. 1D shows various types of differentiated cells induced from the parenchymal progenitor tell population, grown in the presence of defined cytokine cocktails. The cytokine concentrations used were 10 ng/ml (stems cell factor) (SCF), 2 ng/ml interleukin-3 (IL3), 100 ng/mJ macrophage colony stimulating factor (MCSF), and 30 ng/ml platelet-derived growth factor (PDGF)."

This aspect of the Baksh et al. invention teaches culturing of non-hematopoietic cells in the presence of a serum-free medium.

"[0063] The invention relates to human progenitor cells from which a variety of non-hematopoietic cell types can differentiate. Because of the variety of non-hematopoietic cells that can differentiate from the present progenitor cell population, it is referred to herein as a population of non-hematopoietic progenitor a cells. Such a population comprises mesenchymal progenitor cells (MPCs), as well as other non-hematopoietic progenitor cells. Such progenitor cells may also be referred to as "precursor" cells, and these terms are considered equivalent herein for the reason that both progenitors and precursors are able to give rise to differentiated cell type. [0064] The present progenitor cell population results from the non-static suspension culturing of cells of the type obtained from bone marrow, using techniques that are described in greater detail in the examples herein. It is to be appreciated that her comparable and known sources of such progenitor cells can also be used, as noted hereinabove, including particularly umbilical cord and placental blood, peripheral blood, skin, adipose, and muscle. [0065] In order to expand progenitor cells within a cell population, the present invention applies a non-static approach to culturing. This is distinct from established methods that are static, and which are designed not to disturb cells undergoing expansion." This aspect of Baksh et al. reads on instant claim 1 wherein it recites a non-static non-adherent suspension.

The methods of Baksh et al. comprise wherein the input population of cells comprise CD45- and CD45+ cells, the descriptions for Figures 6 and 7 of page 9.

In a preferred embodiment, Baksh et al. disclose the following: "1. An enriched progenitor cell population comprising non-hematopoietic progenitor cells extractable from bone marrow, wherein the cell population is substantially devoid of at least one type of hematopoietic progenitor cell. 2. An enriched progenitor cell population according to claim 1, characterized by the absence of at least one hematopoietic progenitor cell type, wherein said cell type is one having a surface marker selected from CD3, CD14, CD39, CD45, CD66, CD119. " (See claims of publication).

In another specific embodiment of Baksh et al., the following is described: "[0123] FIG. 4F illustrates the expansion of CFU-O colonies over the time period from the treatment conditions described in FIGS. 3A-D. As can be seen, both the no cytokine and SCF+IL3 treatment groups showed quantifiable levels of expansion where as the SCF+PDGF and PDGF treatment groups did not yield any bone colonies. FIGS. 4A and 4B show dark field micrographs of developing nodular areas associated with the no cytokine and SCF+IL3 groups. FIGS. 4C and 4D show no nodular areas associated with the cells retrieved from the SCF+PDGF treatment (such results were also observed for the PDGF treatment, data no shown). The tetracycline signals associated with the mineralized areas were quantified and normalized to the input CFU-O signal, as shown in FIG. 4E. As can be seen, the SCF+PDGF and PDGF groups show a tetracycline signal, however, this signal is associated with the random deposition of mineral throughout the culture dish, which can be described as dystrophic mineralization. Similar experiments were performed on No Cytokine, SCF+IL3 and SCF+IL3+PDGF suspension bioreactors whereby cells were removed instead at 1, 2 and 3 weeks (FIGS.

4F and 4G). It is apparent that the SCF-IL3 and SCF+IL3+PDGF conditions (4F) resulted in a greater tetracycline signal at 3 weeks when compared to controls (4G)."

Absent evidence to the contrary, since the Baksh et al. reference teaches the culturing of non-hematopoietic progenitor cells, wherein the population comprises mesenchymal cells, and further wherein the population was grown in the presence of SCF and IL3, would produce the isolated mesenchymal cells recited in instant claim 9, which are CD45-/CD123+.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633